FORM PTO	O-1390 U.S. DEPARTMENT OF CON	MMERCE PATENT AND TRADEMARK OFFICE	ATTORNEY 'S DOCKET NUMBER
		R TO THE UNITED STATES	GJE-75
		TED OFFICE (DO/EO/US)	U.S. APPLICATION NO (If known, see 37 CFR 1 5
		NG UNDER 35 U.S.C. 371	09/889940
1	RNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
	GB 00/00208	26 January 2000	26 Jan. 1999; 23 July 1999
	E OF INVENTION DE FOR PROTECTING WOUNDS	ONLIMBO	
	ICANT(S) FOR DO/EO/US	ON LIMRS	
Stephen	n George Édward Barker		
Applica	ant herewith submits to the United Sta	ates Designated/Elected Office (DO/EO/US)	) the following items and other information:
1.1		s concerning a filing under 35 U.S.C. 371.	
2.		NT submission of items concerning a filing u	
3.	items (5), (6), (9) and (21) indicated		
		iration of 19 months from the priority date (A	Article 31).
5.	· · · · · · · · · · · · · · · · · · ·	tion as filed (35 U.S.C. 371(c)(2)) d only if not communicated by the Internation	and Durani
Ì	<ul><li>a.  is attached hereto (required</li><li>b.  has been communicated by</li></ul>		nai Bureau).
	===	y the international Bureau. lication was filed in the United States Receivi	vina Office (RO/US).
6. 🗀	<del></del>	he International Application as filed (35 U.S.	
٠. ــ	a. is attached hereto.	te tittetinguonai / spp	.C. 371(0)(2)).
		itted under 35 U.S.C. 154(d)(4).	
7. 🗌		ternational Aplication under PCT Article 19 (	(35 U.S.C. 371(c)(3))
	a. are attached hereto (require	ed only if not communicated by the Internation	ional Bureau).
	b.  have been communicated by	by the International Bureau.	
	c. have not been made; howe	ever, the time limit for making such amendme	ents has NOT expired.
	d. have not been made and wi	ill not be made.	
8.	An English language translation of the	he amendments to the claims under PCT Artic	icle 19 (35 U.S.C. 371 (c)(3)).
1 —		or(s) (35 U.S.C. 371(c)(4)), unsigned.	
	An English lanugage translation of the Article 36 (35 U.S.C. 371(c)(5)).	he annexes of the International Preliminary E	Examination Report under PCT
Iten	ms 11 to 20 below concern document	t(s) or information included:	
11.	An Information Disclosure Stateme	ent under 37 CFR 1.97 and 1.98.	
12.	An assignment document for recor	rding. A separate cover sheet in compliance	with 37 CFR 3.28 and 3.31 is included.
13.	A FIRST preliminary amendment.		
14.	A SECOND or SUBSEQUENT pr	eliminary amendment.	
15. 🗌	A substitute specification.		
16.	A change of power of attorney and	l/or address letter.	
17.	A computer-readable form of the se	equence listing in accordance with PCT Rule	e 13ter.2 and 37 CFR 1.821 - 1.825.
18.	A second copy of the published int	ternational application under 35 U.S.C. 154(d	d)(4).
19.		uage translation of the international application	ion under 35 U.S.C. 154(d)(4).
20.	Other items or information:	. A state of the s	
PCT	Request Form PCT/RO/101		

page 1 of 2

y .	•			JC17 Rec	d PCT/PTO 2	5 JUL 2001
U.S. APPLICATION NO (if kno	NOTE, See 37 CFR 1 5)	INTERNATIONAL AI PCT/GB 0			ATTORNEY'S D	OCKET NUMBER E-75
21. The follow	ing fees are submi	tted:			CALCULATIONS	PTO USE ONLY
BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):  Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO						,
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO\$860.00				ļ		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO						
International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4)\$690.00						
International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4)				\$860.0	00	
Surcharge of \$130.0 months from the ear	0 for furnishing the	e oath or declaration ity date (37 CFR 1.4	n later than [492(e)).	20 30	\$0.0	00
CLAIMS	NUMBER FILE			RATE	\$	<del></del>
Total claims	20 - 20			x \$18.00	\$0.0	00
Independent claims	2 - 3	= 0		x \$80.00	\$0.0	0
MULTIPLE DEPEN	DENT CLAIM(S)	(if applicable)		+ \$270.00	\$0.0	00
	TOT	AL OF ABOVE	E CALCUI	LATIONS =	\$860.0	0
Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.				\$0.0	00	
			SU	BTOTAL =	\$860.0	00
Processing fee of \$130.00 for furnishing the English translation later than 20 30 months from the earliest claimed priority date (37 CFR 1.492(f)).			\$0.0	00		
TOTAL NATIONAL FEE = \$860.00					00	
Fee for recording the accompanied by an	Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property + \$0.00					
TOTAL FEES ENCLOSED =				\$860.0	0	
					Amount to be refunded:	\$
					charged:	\$
a. A check in	the amount of \$		_ to cover the	above fees is enclose	sed.	
b. Please charge my Deposit Account No. 19-0065 in the amount of \$ 860.00 to cover the above fees.  A duplicate copy of this sheet is enclosed.						
c. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 19-0065. A duplicate copy of this sheet is enclosed.						
d. Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.						
NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status.						
	IDENCE ADDRE			Day	id Salin	anchik
CUSTO	MER NUMB	ER	Lab. 05. 0	SIGNATU Oo4 David F	R. Saliwanchik	
	23,557		July 25, 2	NAME 31,794		
					ATION NUMBER	

July 25, 2001

PRELIMINARY AMENDMENT Patent Application Docket No. GJE-75

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s)

Stephen George Edward Barker

Docket No.

GJE-75

For

DEVICE FOR PROTECTING WOUNDS ON LIMBS

Box PCT

**Assistant Commissioner for Patents** 

Washington, D.C. 20231

## PRELIMINARY AMENDMENT

Sir:

Please amend the above-identified patent application as follows:

## In the Claims:

Please cancel all pending claims 1-10 in the subject application.

Please add the following new claims 11-30:

- 11. A device for protecting a wound on a limb wherein said device comprises an enclosure comprising a plastic material, wherein said enclosure has a closeable opening at an end thereof, and wherein said device further comprises a fastening means to enable the opening of said enclosure to be closed around the limb with an affected part of the limb contained within said enclosure; and wherein said device further comprises a fluid-absorbent material within said enclosure.
  - 12. The device according to claim 11, wherein said enclosure is gas-impermeable.
- 13. The device according to claim 11, wherein said plastic material is of a multi-layer plastic construction including a gas-impermeable layer.

- 14. The device according to claim 13, wherein said multi-layer construction further comprises an odor-absorbent layer.
- 15. The device according to claim 12, wherein said enclosure further comprises a means for venting gases through the enclosure.
- 16. The device according to claim 15, wherein said venting means is in association with an active filter.
- 17. The device according to claim 13, wherein said enclosure further comprises a means for venting gases through the enclosure.
- 18. The device according to claim 17, wherein said venting means is in association with an active filter.
- 19. The device according to claim 14, wherein said enclosure further comprises a means for venting gases through the enclosure.
- 20. The device according to claim 19, wherein said venting means is in association with an active filter.
  - 21. The device according to claim 11, wherein said enclosure is water vapor-permeable.
- 22. The device according to claim 11, wherein said enclosure is in the general shape of a sock or boot.
- 23. The device according to claim 22, wherein said enclosure further comprises a non-slip sole.

- 24. The device according to claim 11, wherein said enclosure further comprises a burstable sachet within the enclosure, wherein said sachet comprises an agent suitable for treating burns.
- 25. The device according to claim 11, wherein said plastic material is pliable and has a soft feel.
- 26. The device according to claim 11, wherein said plastic material is at least partially transparent.
- 27. A method for treating a limb having a wound, wherein said method comprises placing a wounded limb within a device for protecting the wounded limb wherein said device comprises an enclosure comprising a plastic material, wherein said enclosure has a closeable opening at an end thereof, and wherein said device further comprises a fastening means to enable the opening of said enclosure to be closed around the wounded limb; and wherein said device further comprises a fluid-absorbent material within the enclosure; wherein said method further comprises closing the opening of said enclosure so that an affected part of said wounded limb is contained within said enclosure.
  - 28. The method according to claim 27, wherein said enclosure is gas-impermeable.
- 29. The method according to claim 27, wherein said plastic material is of a multi-layer plastic construction including a gas-impermeable layer.
- 30. The method according to claim 29, wherein said multi-layer construction further comprises an odor-absorbent layer.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Respectfully submitted,

David R. Saliwanchik

Patent Attorney

Registration No. 31,794

Phone No.: 352-375-8100 Fax No.: 352-372-5800

Address: Saliwanchik, Lloyd & Saliwanchik

David Saliwanchik

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Gainesville, FL 32606-6669

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#### PROTECTIVE COVER FOR INJURED LIMBS

#### Field of the Invention

This invention relates to a device for the protection of wounds on the human body and is concerned primarily with a device for protecting open wounds, such as ulcers, burns or traumatised or gangrenous tissue, for example on the hands, lower limbs and the feet.

#### Background of the Invention

In the United Kingdom at least, approx. 0.5 to 1% of the population at any one time suffers with venous and/or arterial ulceration affecting the lower limbs. Despite often vigorous treatments, either in hospital or by nurses in the community, leg ulcers may remain for several years. Often, even when healed, ulcers can recur and/or remain unhealed for many years. They also cause social problems, since the odour caused by infection is severe, and isolates the sufferer.

Typically, such a wound requires cleaning and dressing from twice daily to twice weekly, using expensive lotions and dressings, e.g. compression bandages, which often prove to have limited efficacy. The treatment is often very labour-intensive, in hospitals and even more so to the district nursing service.

In summary, the treatment of leg ulcers is expensive and often, has little or no effect. In addition, there are other types of wounds on limbs or stumps that require effective care. These include ulcers or wounds caused by diabetes, skin cancer or rheumatoid arthritis.

For example, a typical treatment for hand wounds and, in particular, burns is to clean the 'wound', then place the hand into a plastic bag and tip in either liquid paraffin or Flamazine (a topical antibiotic cream). In concept, the 'bag' protects the hand from trauma/secondary contamination, allows free movement of fingers ('auto-physiotherapy') and hence part-prevention of contractures, and allows visualisation of the hand. Often, a bag cannot easily be found, the medication cannot easily be found, and tape, to secure the bag, is wrapped so tightly that getting the bag off is difficult. Furthermore, all these same problems are encountered when the bag needs changing, especially if this is to be done in the home environment.

By way of example, an Accident & Emergency Department serving a catchment population of 180,000, sees between 1 and 3 persons per week having such hand wounds. Each requires once or twice daily dressings for an average of 10-12 days.

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GB-A-2265314 discloses a protective article for securing around a body part, specifically an arm or leg. It comprises an inflatable protective shield formed from a breathable thermoplastic polyester urethane film, with a sealable cuff.

#### Summary of the Invention

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According to the invention, a device comprises an enclosure of a plastics material, having an opening at an end thereof with fastening means to enable the opening to be closed around a limb (or stump) with an affected part contained within the enclosure, and including a fluid-absorbent material within the enclosure. Such a device can facilitate the protection (and potentially also healing), of wounds by providing a beneficial environment around the wound.

According to a preferred aspect of the invention, a device that may be fitted around the end of a limb comprises an enclosure generally defined by a gas-impermeable or, perhaps, water vapour-permeable plastic material, the enclosure having an opening with fastening means, to enable the opening to be closed around a limb with an affected part contained within the enclosure, and another part, e.g. the opposed end of the enclosure having an internal lining of a fluid-absorbent material. An extra fluid-absorbent pad (or pads) may be positioned within and attached to the enclosure. An active filter (e.g. of charcoal) may be provided in association with means to vent gases through the wall of the enclosure and to reduce odours.

#### Description of the Invention

A device of this invention is intended to be applied around the end of limbs or limb stumps. For convenience, it may be described herein as a glove, sock or boot. In particular, a device intended to be fitted around a leg may be shaped as a sock or boot.

A device of the invention is intended for therapeutic use. It may be included within a sterile pack, for 'field' use.

The plastics material of the enclosure may comprise, for example, a 75  $\mu m$  ethyl methyl acrylate film. Such material is pliable and has a soft feel, for patient comfort.

In a preferred embodiment, the plastic material of the enclosure comprises a multi-layered construction of plastics, e.g. 3, 5 or 7 layers. There may be one or more intermediate layers of PVDC, EVOH or other material that resists the passage of gas. The plastic material may include a layer which is absorbent to odours, especially for use with leg ulcers. Such materials are used in the food-packaging industry. The

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outer layers will conveniently be of EVA or LDPE; such materials allow the enclosure to be formed from two sheets which are welded around their peripheral edges. A different material may be used, which is water-vapour permeable, but still has anti-odour properties.

The enclosure is preferably at least partially transparent, so that the wound is visible to the patient, nurse or physician. This is very practical in hospitals, since it avoids the need for the wound to be exposed on a consultant's visit, when that may not be otherwise considered necessary.

The absorbent lining material may be paper-based or, preferably, is of superabsorbent material. It is suitably attached to the enclosure by transverse weld lines. The opening in the enclosure may also include an internal absorbent lining, forming a "cuff". The fluid-absorbent material is provided in order to reduce the degree of excoriation of the limb part or stump, caused by the continual presence of water.

The fluid-absorbent pad(s) may be of a kind known for their super-absorbency. The active filter may comprise a charcoal material and may incorporate a valve adapted to relieve internal pressures that would otherwise cause ballooning of the enclosure.

The enclosure may also include a connection through which oxygen or other gases may be introduced into the enclosure. Hyperbaric oxygen is useful when a wound is infected by certain anaerobic organisms.

For use on the foot, the outer part of the enclosure opposite to the open end may have a reinforced part. More specifically, an external non-slip layer may be provided.

If desired, the device may include within, or have attached on to it, a capsule or pouch containing an agent such as liquid paraffin or Flamazine, and which may have a breakable seal, allowing release of the agent as required. Alternatively, an agent of this type may be applied when the device is changed.

A device according to this invention may be used to treat open wounds on the feet or legs of a body. For this purpose, the wound is first simply cleaned and the relevant limb enclosed within the device, to provide a substantially air-tight enclosure around the wound.

A device according to this invention can provide a warm and moist environment with adequate oxygenation, whilst maintaining the wound clean, without gross contamination occurring. The device is capable of containing odours. It can be

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tolerated by the patient who can be kept mobile (if appropriate) whilst wearing the device and avoiding aggravation of the condition.

The device is simple enough that, as necessary, it can be reapplied by the patient, perhaps more than once a day. However, it may be unnecessary to change the device so often, once again saving nursing care.

The invention will now be described by way of example only with reference to the accompanying drawings. In the drawings:

Fig. 1 shows a wound-protecting boot embodying the invention, in flat form and in side elevation:

Fig. 2 shows the embodiment of Fig. 1 in section on X-X;

Fig. 3 shows a wound-protecting glove/sock embodying the invention, in flat form and in side elevation;

Fig. 4 shows the embodiment of Fig. 3 in section on Y-Y;

Fig. 5 is a part view of the attachment tape viewed from Z in Fig. 3;

Fig. 6 shows an alternative arrangement for the cuff of the embodiment of Fig. 3; and

Fig. 7 shows the alternative cuff construction of Fig. 6 in section.

Figs. 1 and 2 show a boot device for the protection and treatment of open wounds, and particularly for the protection and treatment of venous ulcerative disease of the lower limbs or gangrenous tissue. The boot is formed from two superimposed sheets of plastics material A and B, joined together by means of heat-sealing along edges C. The edges of the sheets are not sealed at the top end D which thus forms an opening for entry of a limb into the boot. In one construction, a single sheet is used with the side opposed to the end D folded over rather than being welded. The fold could, of course, be along another side.

The sheets each comprise a barrier film of the type which is used in the food packaging industry and for ostomy applications. Such films are generally multi-layered with a middle barrier layer being of, for example, a PVDC or a EVOH material. The sheets are mostly transparent, to allow the relevant area to be visually inspected.

The inner surfaces of the sheets A and B at the open end D include an absorbent layer E extending from the line E1 to the end D and secured by line welds E2 and E3. The end D may be fastened by pulling snugly around the limb and securing by means of a tab D2. This tab may have a peel-off paper layer covering an

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adhesive which can be pressed onto the outer surface of the boot, thus providing a snug fit around the limb.

The lower end of the boot has a similar lining F of comfortable, absorbent material on the inside surface. This lining extends between a securing weld F1 and the edge weld C, with an intermediate weld connection F2.

The inside surface of the boot includes a pad (or pads) of a super-absorbent material G retained by an overlaid porous paper membrane H and secured by a peripheral weld J. A small aperture K in the side is closed internally by a charcoal filter pad L which prevents the boot from ballooning and controls odour. A further aperture M in the side is closed by a rubber diaphragm N acting as a valve which permits oxygenation if required and by a suitable connection.

A reinforcing strip of plastics material P is provided adjacent the top D. This strip may include identifying markings.

The transparent plastics enclosure allows the wound to be inspected. The enclosure provides a warm environment and retains moisture. Excessive moisture is absorbed by the pad material F in the foot part of the boot, and by the material E in the upper part.

Oxygenation may be enhanced by feed through the diaphragm N, and this may be particularly desirable for the treatment of anaerobic organisms. Odour is controlled by the charcoal filter L (which also permits the interior to breathe) as well as by the inherent odour-absorbing properties of the middle laminate layer of the plastics material.

In use, the boot will normally be changed on a once or twice daily basis, and the wound area cleaned using saline. The boot is then applied and secured by the adhesive tab(s) D2 around, for example, the leg. In hospital, this procedure may take up to 5 minutes of a nurse's time; conventional dressings for leg ulcers often take 20-30 minutes to change.

The construction permits the patient to change his or her own device, at home. It also allows the patient to be freely ambulatory, especially if the outer surface at the foot includes a non-slip coating or layer.

Figs. 3 and 4 show a glove/sock device for the protection and treatment of open wounds and burns. The glove/sock is formed from two sheets of plastics material 1a and 1b joined together by means of heat-sealing or radio frequency-welding along the edges 1c. The edges of the sheets are not sealed at the (shaped)

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top and 1e which thus forms an opening for entry of a limb into the device. The other end 1d is formed by folding over the sheets which may then be formed from one piece.

The inner surfaces of the sheets at the open end 1e include a comfortable, absorbent paper layer 2 secured by line welds 2a. The end 1e may be fastened by pulling snugly around the limb and securing by means of a tab(s) T having a portion T3 attached to the cuff. The tab(s) T have a peel-off paper layer T1 removed by a pull-tab T2 and covering an adhesive which can be pressed onto the outer surface of the glove, thus providing a snug fit around the wrist.

As shown in Figs. 6 and 7, the inside surface of the glove may include a partially or fully circumferential pad 5 of a super-absorbent material retained by an overlaid porous paper membrane and secured by a peripheral weld 5a.

Especially for the treatment of burns, the glove may include burstable sachets within the enclosure, containing Flamazine or any other suitable agent. Alternatively, sachets of such material, ready for use, may be attached to the outside of the glove.

In use, the glove will normally be changed on a regular basis and perhaps several times per day, and the affected area cleaned using saline. The glove/sock is then applied and secured by the adhesive tab(s) T around for example, the wrist. The mostly transparent, soft plastic allows the wound to be inspected. The plastic provides a warm environment and retains moisture, excessive moisture being (super-) absorbed by the pad material 5 and by the material 2.

Whether the invention is embodied by the relatively simple glove/sock of Figs. 3-7 or by the boot of Figs. 1-2, such devices are simple and economical to construct, and easy to use. They can readily be constructed in a range of different sizes.

Remarkably, devices of the invention may have a beneficial therapeutic effect. This has been demonstrated in the case of a leg ulcer that had been treated by conventional methods for several months; after this time, the wound remained unsightly and produced a disgusting odour. After just one week's usage of the boot illustrated in Figs. 1-2, by the simple protocol described above, i.e. without dressings, both appearance and odour had improved; after another 10 days, infection had gone, and the wound had evidently started to heal.

More particularly, the boot has been used on 8 patients, one bilaterally, making a total of 9 legs. The mean age of the patients was 70 years (range 40-88 years). In

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5 patients, the boot was used for one week. In two cases, it was discontinued after 3 days.

The aetiology of the ulcers was: 3 mixed arterio-venous, 1 secondary to pressure necrosis, 1 'trash foot' secondary to drug abuse, 1 venous and 2 arterial. 3 patients were diabetic.

The length of time patients had had their ulcers ranged from 2 weeks to 6 years. Previous ulcer treatment had been simple dressings in all cases, Granuflex being used in 6 cases, jelonet in one and dry dressings in 1, all associated with additional gauze and crepe bandages.

The time taken to clean the ulcers ranged from 15 to 30 minutes per dressing change, which averaged 2 or 3 dressings per day. Wound swabs were taken in all cases. *Pseudomonas* was grown from 4 ulcers and *Staphylococcus aureus* from 3 limbs.

In each case, it took no more than 6 minutes to remove the boot, clean the ulcer and re-apply. There was an obvious improvement in 4 ulcers, with one limb becoming appropriate for application of a split skin graft (previously, the limb had been considered more likely to be amputated). In 2 cases, there was no discernible difference. The odour from infected ulcers was markedly improved in all cases.

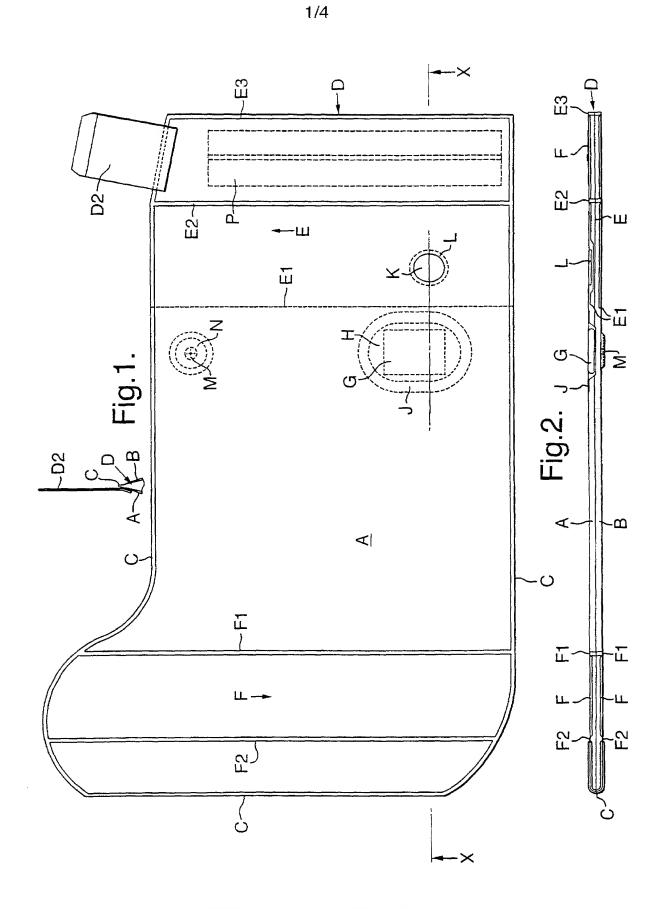
5 Patients said the boot was comfortable or very comfortable to wear, 2 said it was uncomfortable (one had boots bilaterally) and one patient was unable to comment due to medical health. Fluid collection was the only problem, and can be readily rectified by the provision of absorbent padding.

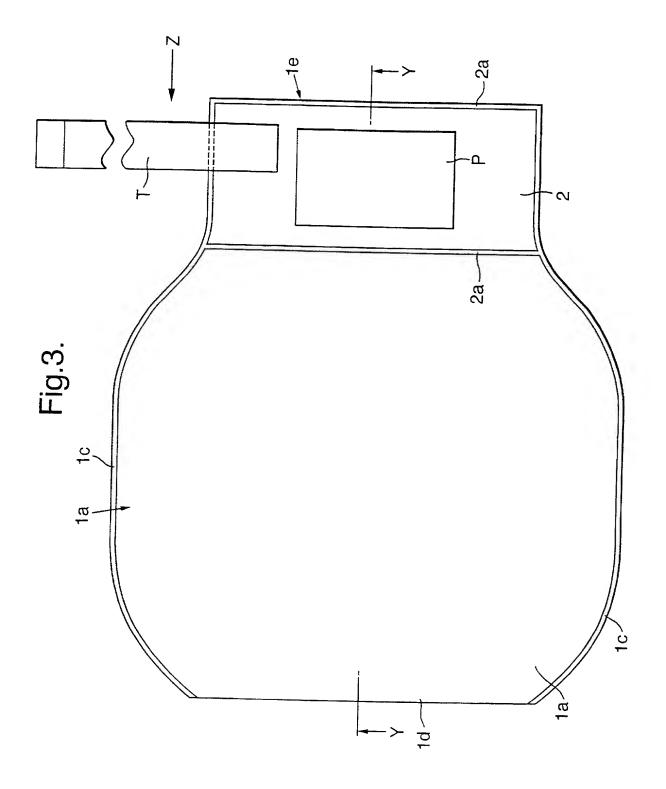
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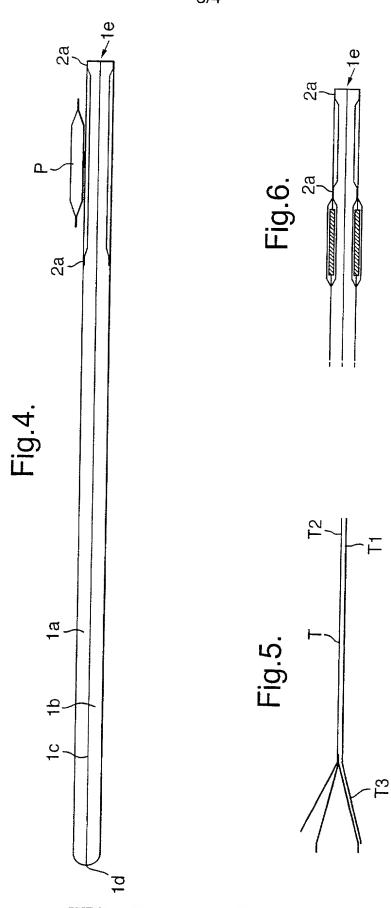
### CLAIMS

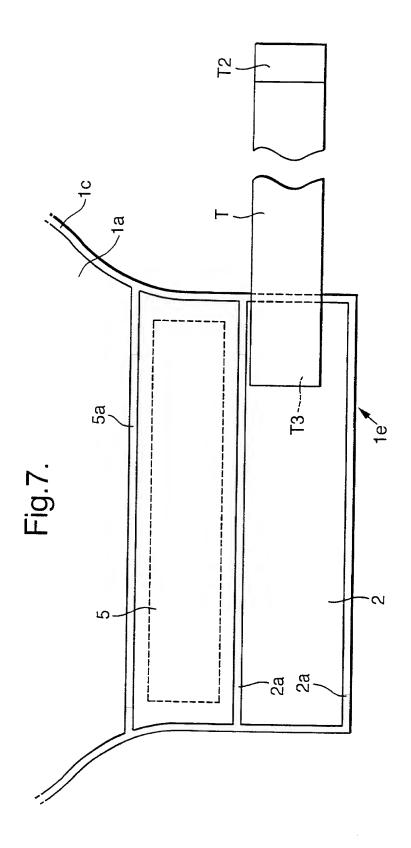
- 1. A device which comprises an enclosure of a plastics material, having an opening at an end thereof with fastening means to enable the opening to be closed around a limb or stump with an affected part contained within the enclosure, and including a fluid-absorbent material within the enclosure.
- 2. A device according to claim 1, wherein the enclosure is gas-impermeable.
- 3. A device according to claim 1, wherein the enclosure is of a multi-layer plastics construction including a gas-impermeable layer.
- 4. A device according to claim 3, wherein the construction includes an odourabsorbent layer.
  - 5. A device according to any of claims 2 to 4, wherein the enclosure includes means to vent gases through its wall.
  - 6. A device according to claim 5, wherein the venting means is in association with an active filter.
- 15 7. A device according to any preceding claim, wherein the enclosure is water vapour-permeable.
  - 8. A device according to any preceding claim, which is in the general shape of a sock or boot.
  - 9. A device according to claim 8, which additionally comprises a non-slip sole.
- 20 10. A device according to any preceding claim, for use in therapy.





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## **DECLARATION AND POWER OF ATTORNEY**

As a below-named inventor, I hereby declare that my residence, post office address and citizenship are as stated below next to my name; I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of subject matter which is claimed and for which a patent is sought on an invention entitled PROTECTIVE COVER FOR INJURED LIMBS

the specification of which is attached hereto or						
was filed on 26 JAN 2000 as United States Application Number or PCT International Application Number PCT/GB00/00208 and was amended on 04 DEC 2000 (if applicable						
I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above. acknowledge the duty to disclose information which is material to patentability as defined in 37 CFF 1.56. I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for a patent or inventor's certificate, or PCT international application having a filing date before that of the application or which priority is claimed:						
Prior Foreign Application Number(s)	Country	Foreign Filing Date	Priority Not Claimed	Certified Attache YES		
9901711.3	GB	26 JAN 1999				
9917445.0	GB	23 JUL 1999				
9917443.5	GB	23 JUL 1999				

As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: David R. Saliwanchik, Reg. 31,794; Jeff Lloyd, Reg. 35,589; Doran R. Pace, Reg. 38,261; Christine Q. McLeod, Reg. 36,213; Jay M. Sanders, Reg. 39,355; James S. Parker, Reg. 40,119 and Jean E. Kyle, Reg. 36,987; Frank C. Eisenschenk, Reg. 45,332; Seth M. Blum. Reg. 45,489

Direct all correspondence to:
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2421 N.W. 41st Street, Suite A-1
Gainesville, FL 32606-6669
USA

jeopardise the validity of the application or any patent issued thereon.			
and the state of t	·10		
Full name of sole or First Inventor	Stephen George Edward	BARKER	
Inventor's signature	Mark		
Residence address	London, United Kingdom	CBN	
Post Office address			
	The Vascular Unit, Dept. The Middlesex Hospital, United Kingdom		
Country of Citizenship	United Kingdom	Date of signature	20/7/01

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C 1001 and that such willful false statements may